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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,489	02/15/2002	Franciscus Antonius Maria Rijsewijk	454313-2280.1	5246

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

10/077,489

Applicant(s)

RIJSEWIJK ET AL.

Examiner

Anne Marie S. Wehbe

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--Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 29 September 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached.

3. ☒ Applicant's reply has overcome the following rejection(s): see attached.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 68-107.

Claim(s) objected to: _____.

Claim(s) rejected: 16-62, 64-66.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ATTACHMENT TO ADVISORY ACTION

2. CONT. The amendments to the specification and to the claims to introduce the language “mammalian viral promoter” constitute new matter which is not supported by the specification. The applicant points to page 7 of the specification, the text of the preliminary amendment in the instant application and more specifically to column 2, lines 52-53 of U.S. Patent No. 5,846,946, which applicant states was incorporated by reference into the present application, for support for the proposed amendments. Page 7 of the instant specification recites the use of a “strong eukaryotic promoter”. Neither this section, nor any other portion of the specification refers to a mammalian promoter or to a mammalian viral promoter in particular. Although the CMV promoter was given as an example, the CMV promoter is a specific species of promoter which is not equivalent to the genus of “mammalian viral promoter”. The preliminary amendment submitted with the filing of the instant application lists the priority information for the instant application and further contains the statement that the priority documents and other documents cited in the specification are “incorporated herein by reference”. The preliminary amendment also added a paragraph which states that, “the protein encoded by the inserted nucleotide sequence is capable of being expressed in the cells and of bringing about the development of an immune response (See also U.S. Patent Nos 5,846,946,”. The amended sections do not recite the use of mammalian viral promoters, and from the context of the paragraph quoted above it would appear that U.S. Patent No. 5,846,946 has been referenced in regards to general methods of expressing proteins in cells which lead to the development of immune responses. While column 2, lines 52-53 of U.S. Patent No. 5,846,946 does disclose that a mammalian viral promoter can drive the expression of an antigen from a eukaryotic cell, there is nothing in the instant specification that points to this particular teaching of U.S. Patent No. 5,846,946. The MPEP states that while material essential to describe the claimed invention and provide an enabling disclosure of the invention may be incorporated by reference to a U.S. Patent, “mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph” MPEP 608.01(p). The MPEP states that, “ In addition to other requirements for an application, the referencing application should include an identification of

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the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found" MPEP 608.01(p). The preliminary amendment to the specification makes a blanket statement that documents cited in the specification are "incorporated herein by reference". However, the specification does not identify the subject matter of the U.S. Patent No. 5,846,946 that is relevant to the instant invention or particularly point out which parts of the referenced patent are to be incorporated. As such, the disclosure of U.S. Patent No. 5,846,946 cannot be relied upon to provide specific support for the proposed amendment to the specification.

3. CONT. The terminal disclaimer filed by applicant's has overcome the double patenting rejection over claims 16-62, 64-66, and 68-107.

5. CONT. The rejection of claims 16-62, and 64-66 under 35 U.S.C. 112, first paragraph, is maintained. Applicant's arguments are based on the entry of the proposed claim amendments. Since the instant amendment has not been entered, the arguments based on these amendments is not persuasive.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday-Friday from 10:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 872-9306. Please note that Official papers can no longer be received by the examiner's direct Rightfax number.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

